IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

Kathryn Kiker, et al., Plaintiffs, vs. SmithKline Beecham Corporation d/b/a GlaxoSmithKline LLC, Defendant.	:	Case No. 2:14-cv-02164-EAS-TPK Chief Judge Edmund A. Sargus, Jr. Magistrate Judge Terence P. Kemp

DEFENDANT GLAXOSMITHKLINE LLC'S MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OF ITS 2012 PLEA AGREEMENT, CIVIL SETTLEMENT AGREEMENTS, AND ASSOCIATED DOCUMENTS (ORAL ARGUMENT REQUESTED)

Defendant GlaxoSmithKline LLC ("GSK") submits its Motion *in Limine* to Exclude Evidence of its 2012 Plea Agreement, Civil Settlement Agreements, and Associated Documents because such evidence is irrelevant, prejudicial, and inadmissible.

I. INTRODUCTION

Plaintiffs intend to offer evidence of GSK's 2012 plea agreement with the United States government (the "Government"), the Government's Information containing its allegations against GSK in that criminal proceeding (the "Information"), three associated civil settlement agreements between GSK and the Government resolving claims under federal and state False Claims Acts, the complaints regarding the False Claims Act, and a Corporate Integrity Agreement ("CIA") between GSK and the Office of the Inspector General ("OIG").[1,2] GSK seeks an order precluding Plaintiffs and their experts from presenting any such evidence at trial.

[1] *See, e.g.*, Plfs' Deposition Designations (Doc. 158) at 23-30, 48 (designating testimony of Mr. O'Connor and Mr. Collier, who gave depositions in *Orrick v. GSK* on matters related to GSK's 2012 plea agreement); Plfs' Exhibit List (Doc. 159) at 138-139 (listing GSK's 2012 plea agreement, the Government's Complaint, complaints regarding the

II. ARGUMENT AND CITATION OF AUTHORITY

A. Evidence Regarding the 2012 Plea Agreement, Information, Civil Settlement Agreements, and CIA Is Not Relevant to this Lawsuit.

Evidence that is not relevant is not admissible. FED. R. EVID. 402. To establish relevance with respect to other lawsuits, governmental investigations, or charges Plaintiffs must show that the circumstances involved in those other matters are "substantially similar" to the circumstances involved in this case. *Buck v. Ford Motor Co.*, 526 F. App'x 603, 606-07 (6th Cir. 2013) (affirming exclusion of other accidents where the plaintiff did not show that they were substantially similar); *see also McLeod v. Parsons Corp.*, 73 F. App'x 846, 854 (6th Cir. 2003) (holding that for other acts to be admissible, they "must be similar enough and close enough in time to be relevant" and affirming exclusion of other lawsuits because there was "no clear nexus between these lawsuits and this case"). Plaintiffs cannot make this showing.

1. The Plea Agreement and Information Are Not Relevant.

With respect to Paxil, GSK was charged with and pled guilty to one no-intent ***misdemeanor*** count of "misbranding" under the federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. (*See generally* Information, *United States v. GlaxoSmithKline LLC*, Crim. No. 1:12-cr-10206-RWZ, ¶ 1(a) (D. Mass) (attached as Ex. 1)[3]; Plea Agreement, *United States v. GlaxoSmithKline LLC*, Crim. No. 1:12-cr-10206-RWZ (D. Mass.) (attached as Ex. 2).) A drug is misbranded if its labeling[4] is "false or misleading in any particular." 21 U.S.C. §

False Claims Act, the Government's Information, the three associated civil settlement agreements, GSK's CIA, and related press releases and correspondence as Exhibits 4804-4812, 4817-4821, and 4828); *id*. at 141-142 (listing documents related to GSK's plea agreement as Exhibit Nos. 4885-4894, 4915, 4926, 4928-4929, 4931-4939).

[2] GSK agreed to pay $1 billion under the terms of the plea agreement along with $2 billion to resolve its federal and state civil liabilities.

[3] For the convenience of the Court, exhibits are attached to the Declaration of William D. Kloss, Jr., accompanying this Motion.

[4] "Labeling" is not limited to the package insert; it includes all hard-copy promotional material, and everything from booklets to calendars that accompanied a drug if they were designed for use and used in the distribution and sale of

352(a). As a strict liability offense, there is no *scienter* requirement, and the Government did not charge GSK with (and GSK did not admit to) acting with the intent to defraud or mislead anyone. (*See* Ex. 1, Information; Ex. 2, Plea Agreement.)

More importantly, the Paxil misbranding allegations resolved by the plea relate ***solely*** to the promotion of Paxil for use in patients under age 18 – a patient population unrelated to Ms. Kiker. (*See* Ex. 1, Information.) The Information does not include any allegations related to: the use of Paxil during pregnancy; the safety of Paxil during pregnancy; a possible association between Paxil and birth defects; information in Paxil's labeling about the use of Paxil during pregnancy; or marketing of Paxil for use in pregnancy. (*See id*.) The words "pregnancy," "birth defect," and "congenital malformation" appear nowhere in the Information. (*Id*.)

In entering the plea agreement, GSK ***did not admit to all of the allegations in the Information***.[5] (*See* July 5, 2012 Plea and Sentencing Hr'g Tr. at 9 (attached as Ex. 3).) Rather, the conduct to which GSK admitted that formed a factual basis for the plea was limited and discrete. Specifically, GSK admitted that some Paxil sales representatives in January 2001 to January 2002 used slides during promotional calls with physicians that were "misleading" (as that term is used in the FDCA) because the slides discussed the use of Paxil in patients under 18 but did not disclose that Paxil was not approved for use in patients under 18. Like the allegations in the Information, the factual basis for the plea was in no way related to the use of Paxil during

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the drug. *See* 21 C.F.R. § 202.1(l)(2). In this instance, the Paxil "labeling" involved in the plea consisted of slides discussing the use of Paxil in patients under 18.

[5] As part of the same plea, GSK also pled guilty to single strict liability, misdemeanor counts regarding two other GSK drugs (Wellbutrin and Avandia). (*See* Ex. 2, Plea Agreement.) Plaintiffs do not claim any injuries from Wellbutrin or Avandia. Accordingly, GSK's plea with respect to those medications is even further disconnected from Plaintiffs' claims than GSK's plea with respect to Paxil. *See, e.g.*, *Skibniewski v. Am. Home Prods. Corp.*, 2004 WL 5628157, at *4 (W.D. Mont. Apr. 1, 2004) ("evidence relating to different drugs, different injuries, different people and different conditions have no bearing on this case").

pregnancy or any possible association between Paxil and birth defects. (*See generally* Ex. 2, Plea Agreement.)

In sum, the plea agreement and Information have no relevance in this case involving whether Paxil caused C.S.'s VSD or whether GSK adequately warned of potential birth defects associated with Paxil. Thus, the circumstances that gave rise to the plea are not "substantially similar" to the circumstances involved in this case and the required "clear nexus" between the plea and this case is lacking.

2. The Civil Settlement Agreements and Civil Complaints Are Not Relevant.

GSK also entered three civil settlement agreements with the Government, one of which resolved civil claims about the marketing of Paxil and other medications.[6] Like the plea agreement, the allegations in the civil lawsuits with respect to Paxil relate to the promotion of Paxil for use in patients under age 18 and alleged resulting violations of the False Claims Act. (*See* Compl., *United States v. GlaxoSmithKline plc*, C.A. No. 11-10398-RWZ, ¶¶ 3(a), 271-78 (D. Mass.) (attached as Ex. 4).) The civil settlement agreement did not relate to the marketing of Paxil for use in pregnancy. (*See* Settlement Agreement, *United States v. GlaxoSmithKline plc*, C.A. No. 11-10398-RWZ, ¶ F (D. Mass.) (attached as Ex. 5).)

Moreover, GSK expressly made no admissions of facts or wrongdoing in connection with the civil settlement other than the very limited admissions (described above) made in connection with the plea agreement. (*See id.* ¶ H.) In other words, GSK did not admit to any of the numerous allegations contained in the *qui tam* complaints beyond those that form the factual basis for the plea. Thus, the civil settlement agreements, like the plea, are not relevant.

[6] There is no evidence that Ms. Kiker took any other medications covered by this civil settlement agreement. GSK also entered two other civil settlement agreements: (1) a separate agreement resolving allegations about the marketing of Avandia, which Ms. Kiker also did not take, and (2) an agreement resolving allegations about nominal pricing, which is not at issue in this case.

3. The Plea Agreement and Civil Settlement Agreements Are Not Relevant to Plaintiffs' Claims for Fraud or Punitive Damages.

GSK expects Plaintiffs to argue that the 2012 plea, Information, and civil settlement agreements are somehow relevant to Plaintiffs' fraud and punitive damages claims. As a threshold matter, this argument fails because, as discussed above, GSK pled guilty to strict-liability misdemeanors that do not have a *scienter* or "intent" requirement. The plea says nothing about whether GSK acted with actual malice, as required for punitive damages under Ohio law. *See Cabe v. Lunich*, 70 Ohio St. 3d 598, 601 (1994).

Moreover, to admit the plea as somehow probative of punitive damages would violate due process. It is well-established that punitive damages cannot be based on injury the defendant allegedly inflicted on a non-party. *See Philip Morris USA v. Williams*, 549 U.S. 346, 353 (2007) ("[T]he Constitution's Due Process Clause forbids a State to use a punitive damages award to punish a defendant for injury that it inflicts upon nonparties or those whom they directly represent, *i.e.*, injury that it inflicts upon those who are, essentially, strangers to the litigation."); *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 424 (2003) ("The reprehensibility guidepost does not permit courts to expand the scope of the case so that a defendant may be punished for any malfeasance, which in this case extended for a 20-year period.").

4. Evidence Regarding GSK's "New Framework" of Compliance Has No Relevance to Any Issue in This Case.

When GSK announced its agreement in principle as to the 2012 plea agreement and civil settlement agreements, GSK also stated that, since 2008, the company had established a new framework for compliance.[7] (*See* Nov. 3, 2011 Press Release (attached as Ex. 7).) Any evidence related to the "new framework" should also be excluded because it is irrelevant.

[7] In *Rader v. GSK*, the court excluded evidence regarding GSK's "new framework." (*See Rader v. GSK*, Mar. 11, 2016 Order granting GSK's Motion *in Limine* to Exclude Evidence of Other Claims, Lawsuits, Governmental

The new framework was established years ***after*** C.S. was born in 2001. Additionally, the new framework, which was established as part of GSK's continuous improvement to its policies and procedures as part of evolving industry standards, pertains solely to GSK products not at issue here. It was ***not*** created: (1) as the result of any practices or issues that arose regarding the use of or promotion of the use of Paxil in pregnancy; or (2) as a result of any practices or issues that arose regarding a possible association between Paxil and birth defects. Indeed, GSK was no longer promoting Paxil by 2008.

Even if the new framework did pertain to Paxil, which it does not, this evidence would be barred as evidence of a subsequent remedial measure. FED. R. EVID. 407. A primary reason for Rule 407 is to "encourag[e] people to take, or at least not discourage[e] them from taking, steps in furtherance of added safety." FED. R. EVID. 407, Advisory Comm. Notes. Because GSK established the new framework as part of GSK's improvement to its policies after C.S. was born, Rule 407 bars admission of evidence of the new framework. *See, e.g., Cuyahoga Cty. v. State Auto. Mut. Ins. Co.*, 2012 WL 5304083, at *13 (N.D. Ohio Oct. 25, 2012) (Rule 407 bars admission of amendments made to policy after relevant events in case).

B. GSK's 2012 Plea Agreement, Information, Civil Settlement Agreements, and CIA Are Not Admissible For Any Purpose.

Even if Plaintiffs could show that GSK's plea agreement and civil settlement agreements are somehow relevant to their claims – and they cannot – Plaintiffs cannot show that the agreements are admissible for any purpose.

1. The Plea Agreement Is Not Admissible for Impeachment Purposes.

Evidence regarding felonies and any crime whose elements require proof of a dishonest act or false statement may be admissible for impeachment. FED. R. EVID. 609(a). GSK's plea to

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Investigations or Other Charges, Including GSK's 2012 Plea Agreement and Civil Settlement Agreement, which argued that the court should exclude evidence of the new framework (attached as Ex. 6).)

no-intent, strict-liability misdemeanors under the FDCA is inadmissible for impeachment purposes because it does not fall within either category. *See, e.g., United States v. Jones*, 554 F. App'x 460, 472 (6th Cir. 2014) (district court properly found misdemeanor whose elements do not require proof of dishonest act or false statement inadmissible for impeachment purposes).

Additionally, Rule 609 "does not permit corporate convictions to be used to impeach the credibility of employee witnesses who were not directly connected to the underlying criminal act." *Walden v. Ga.-Pac. Corp.*, 126 F.3d 506, 523 (3d Cir. 1997) (district court properly excluded corporate pleas as impeachment evidence where "there was no evidence of such a connection")[8]. None of the individuals who used the slides that formed the factual basis for the plea will be testifying at the trial of this matter. Accordingly, GSK's plea is inadmissible to impeach any individual GSK witness at trial.

2. The Plea and Civil Settlement Agreements Are Not Admissible to Prove GSK Committed Similar Conduct in this Case.

Evidence of alleged prior bad acts is not admissible to prove similar misconduct in another case. FED. R. EVID. 404(b). GSK anticipates that Plaintiffs may argue that the plea and civil settlement agreements are not being offered to show conduct in conformity therewith, but for another purpose, such as GSK's alleged motive, intent, or lack of mistake.

Any such argument fails because it is based on a faulty premise. As explained above, GSK pled guilty to ***strict liability misdemeanors without a scienter or intent requirement***. The Government did not charge GSK with (and GSK did not admit to) acting with the intent to defraud or mislead anyone. Because GSK only pled guilty to strict liability offenses without a

[8] The Sixth Circuit has not ruled on whether a corporation's conviction can be used to impeach an employee. *See Hickson Corp. v. Norfolk S. Ry. Co.*, 124 F. App'x 336, 342-43 (6th Cir. 2005) ("In a matter of apparent first impression in the Sixth Circuit, the question before us is whether Rule 609 permits the use of a corporation's prior criminal conviction to impeach a corporate representative's testimony. …We will not decide in this case whether Rule 609 should be applied in this manner because, like the introduction of the … letter discussed … we believe that the best course of action would been to exclude *any* evidence of [defendant's] environmental record that was not directly related to this incident.").

scienter requirement, the plea agreement is not evidence of any alleged motive, intent, or lack of mistake. Plaintiffs cannot claim that the plea agreement and civil settlement agreements support anything other than Plaintiffs' belief that GSK has the propensity to engage in unlawful conduct. Because the agreements solely would serve the purpose of proving character in conformity with prior bad acts, the Court should exclude them.

3. The Plea and Civil Settlement Agreements Are Not Evidence of Habit.

Plaintiffs may also argue that the plea agreement and civil settlement agreements are somehow admissible as habit evidence. This argument also fails. As an initial matter, ***allegations*** of conduct that GSK ***denied*** cannot be "habit evidence."

Even if GSK admitted to all of the alleged conduct, which it did not do, such evidence would not be admissible to prove that GSK acted in this case in conformity with a habit. A habit is a "regular practice of meeting a particular kind of situation with a specific type of conduct, such as the habit of going down a particular stairway two stairs at a time. . . [t]he doing of the habitual acts may become semi-automatic." FED. R. EVID. 406, Advisory Comm. Notes. This is not the situation with respect to GSK's plea or civil settlement. As detailed above, the factual basis of GSK's plea with respect to Paxil is narrow and limited and does not establish that GSK has any regular marketing practice of any kind, let alone a habit of any particular marketing practice. Accordingly, the plea and civil settlement agreements are not admissible as habit evidence. *See, e.g., Infocision Mgmt. Corp. v. Found. for Moral Law Inc.*, 2011 WL 3022002, at *5 (N.D. Ohio July 22, 2011) (evidence of employee conduct not admissible as habit evidence where party "offers no evidence, beyond its unsupported 'contention,' that the isolated acts of Infocision's employee amounted to a routine practice such that it represented Infocision's 'regular response to a repeated specific situation'").

4. The Civil Settlement Is Inadmissible Evidence of an Offer to Compromise.

Plaintiffs also cannot introduce evidence of GSK's civil settlement to prove liability in this case because courts exclude such evidence to encourage settlements. FED. R. EVID. 408. This exclusionary rule applies to offers of comprise and to final settlements. *See* FED. R. EVID. 408, Advisory Comm. Notes (rule excludes "evidence of conduct or statements made in compromise negotiations, as well as the offer or completed compromise itself").

C. Evidence Regarding the 2012 Plea and Civil Settlement Agreements and the New Framework is Inadmissible Because it is Unfairly Prejudicial.

Even if evidence of the 2012 plea and civil settlement agreements and the new framework were relevant and admissible as to some issue in this case, exclusion is still proper under Rule 403. *See Thomas & Marker Const. Co. v. Wal-Mart Stores, Inc.*, 2008 WL 5054706, at *2 (S.D. Ohio Nov. 20, 2008) ("[E]vidence that arouses the jury's emotional sympathies, evokes a sense of horror, or appeals to an instinct to punish may be unfairly prejudicial.").

Courts in this Circuit have recognized that there is great risk in admitting evidence of previous lawsuits and legal proceedings. *See McLeod*, 73 F. App'x at 854 ("the potential for prejudice that would have accompanied this evidence [of other lawsuits] would have substantially outweighed its probative value, and this evidence would have misled the jury"); *Ross v. Am. Red Cross*, 2012 WL 2004810, at *5 (S.D. Ohio June 5, 2012) ("Unsubstantiated allegations from other individuals, in other cases and under different circumstances, are of minimal probative value" that "is outweighed by the risk that the jury will draw improper conclusion[s]"), *aff'd* 567 F. App'x 296, 308 (6th Cir. 2014). Other jurisdictions agree. *See, e.g., Gil de Rebollo v. Miami Heat Ass'n*, 137 F.3d 56, 64 (1st Cir. 1998) (approving exclusion of conviction from later action because its admission "would have allowed the jury to substitute judgment reached in the criminal proceeding for its own"); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 1994

WL 270252, at *3 n.5 (N.D. Ill. June 16, 1994) (excluding corporate guilty plea in case involving FDA regulated medical equipment in part because any probative value "is substantially outweighed by the danger of unfair prejudice and confusion of the issues"). Admission of evidence regarding GSK's plea would play on the jurors' tendency to conclude that whatever GSK did to warrant the plea was "bad enough" to warrant imposing liability here.

Also, the plea agreement is based on the violation of a federal statute with no analog in state tort law. An attempt by Plaintiffs to rely on the agreements would muddy the legal issues relating to Plaintiffs' claims, and the Court should not allow Plaintiffs to rely on the agreements in lieu of meeting their burden in this case.

Finally, the agreements resolve complex and lengthy investigations. If Plaintiffs were to present evidence regarding the allegations that led to GSK's plea agreement, GSK would have to spend considerable time rebutting those allegations with evidence about what exactly GSK pled guilty to, Paxil's safety and efficacy in the pediatric population, and GSK's marketing practices with respect to pediatric use. This "trial within a trial" would take weeks. Accordingly, exclusion is proper. (*See Adams v. GSK*, June 26, 2012 Mot. Hr'g Tr., June 26, 2012 a.m. session at 68:10-22 (reasoning that a fair presentation of evidence from the Government's investigations of GSK not possible given the undue delay that would result) (attached as Ex. 8).)

III. CONCLUSION

Based on the foregoing, GSK respectfully requests that this Court grant its Motion *in Limine* and enter an Order excluding from trial any evidence of, or reference to, the 2012 plea agreement, Information, civil settlement agreements, CIA, and related documents.

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CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing was served upon all counsel of record, this 24th day of January, 2017, by the Court's electronic service.

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ORDER

AND NOW, this __ day of _____, 2017, upon consideration of Defendant GlaxoSmithKline LLC's ("GSK") Motion *in Limine* to Exclude Evidence of its 2012 Plea Agreement, Civil Settlement Agreements, and Associated Documents, and any response thereto, and having considered the arguments of counsel, it is hereby ORDERED that Defendant's Motion is GRANTED:

(1) Plaintiffs, their counsel, and their witnesses are prohibited from mentioning or bringing before the jury, either directly or indirectly, upon voir dire, opening statement, interrogation of witnesses, argument, objections before the jury or by any other means, or in any other manner, any evidence of or reference to GSK's 2012 plea agreement, Information, civil settlement agreements, CIA, and related documents;

(2) Plaintiffs' counsel are instructed to inform Plaintiffs and all witnesses called by Plaintiffs not to volunteer, interject, disclose, state, mention in the presence of the jury or in any other way refer to GSK's 2012 plea agreement, Information, civil settlement agreements, CIA, and related documents; and

(3) Plaintiffs and their counsel are instructed that a violation of any of the Court's instructions in connection with this Motion would constitute undue harm to GSK's case and would deprive GSK of a fair and impartial trial, and that such violation and failure to abide by this Court's Order may bring about a mistrial and other appropriate relief, including, but not limited to, sanctions.

_____ _____

Date

Edmund A. Sargus, Jr.
Chief United States District Judge